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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------------|----------------------|---------------------|------------------|
| 10/646,539 | 08/22/2003 | Jay Douglas Audett | ARC3254R1/A5033 | 9721 |
| 27777 PHILIP S. JOH | | | | |
| JOHNSON & JOHNSON BLAZA | | | CHANG, VICTOR S | |
| ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | ART UNIT | PAPER NUMBER |
| | · | | 1771 | |
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| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 31 D | AYS | 01/16/2007 | PAI | PER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | | Application No. | Applicant(s) | |
|---|--|---|---|------|
| | | 10/646,539 | AUDETT, JAY DOUGLAS | |
| | | Examiner | Art Unit | |
| | | Victor S. Chang | 1771 | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with th | e correspondence address | |
| WHIC - Exten after: - If NO - Failur Any n | CRTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. It period for reply is specified above, the maximum statutory period we tee to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATI 36(a). In no event, however, may a reply be rill apply and will expire SIX (6) MONTHS for cause the application to become ABANDO | ON. e timely filed rom the mailing date of this communicati DNED (35 U.S.C. § 133). | |
| Status | | | | |
| 2a)☐ 3)☐ | Since this application is in condition for allowan | action is non-final. | • | is |
| | closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, | 453 O.G. 213. | |
| Dispositi | on of Claims | | | |
| 5) _ 6) _ 7) _ | Claim(s) 14-16,18-23 and 25-31 is/are pending 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) 14-16,18-23 and 25-31 are subject to | vn from consideration. | uirement. | |
| Application | on Papers | | | |
| 10) 🗌 - | The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the correction drawing sheet(s) including the correction of the oath or declaration is objected to by the Examiner. | epted or b) objected to by the drawing(s) be held in abeyance. So on is required if the drawing(s) is | See 37 CFR 1.85(a). objected to. See 37 CFR 1.121 | (d). |
| | nder 35 U.S.C. § 119 | | | |
| 12) <u></u> | Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori application from the International Bureau ee the attached detailed Office action for a list of | have been received. have been received in Applicity documents have been rece (PCT Rule 17.2(a)). | ation No ived in this National Stage | |
| 2) | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date | 4) Interview Summa Paper No(s)/Mail 5) Notice of Informa 6) Other: | Date | |

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DETAILED ACTION

Introduction

- 1. Applicants' amendments and remarks filed on 11/13/2006 have been entered. Claims 14, 20 and 31 have been amended.
- 2. In view of the amendment and applicant's comment that the details of a broad claim are not required, the examiner finds that further species election is required, so as to focus on the inventive features of the instant invention for prosecution.

Election/Restrictions

- This application contains claims directed to the following patentably distinct species:
 Structure of the secondary drug reservoir
 - A. the tie layer comprises a secondary drug-containing reservoir, as set forth in claim 14;
- B. the tie layer is an additional layer, as set forth in claim 31.
 The species are independent or distinct because each species has a patentably distinct structure,

and there is no evidence that these species are obvious variants.

Applicant is required under 35 U.S.C. 121 to cleat a single disclosed species for

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there is no generic claim for independent claims 14 and 31.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent. Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor S Chang

Via. Chung

Examiner

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1/8/2007